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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,830	03/31/2004	Charles Edward Baumgartner	134678/YOD GERD:0086	6500

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/814,830

Applicant(s)

BAUMGARTNER ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 18, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by West et al (US6500119).

West et al is directed to the use of physical pressure sensors 14 together with an ultrasound array 15. (i)The physical sensors may provide a visible or audible output indication of engagement pressure (col. 1 line 38 – col. 2 line 19), (ii) such output may be predicated upon an automatic internal threshold comparison (col. 6 line 57 – col. 7 line 19), and/or (iii) such an indication may incorporate into a pressure image for concurrent display with the ultrasound image (col. 8 line 66 – col. 9 line 15. In each case the physical pressure sensors 14 control *something* in the system which is overall an ultrasound system, or in the alternative the reference effectively instructs to

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manually proceed with a measurement, the contact engagement discriminant control being open loop feedback for operator control for proceeding with an imaging study.

Claims 1- 3, 5, 7, 18, 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Hiruta et al (US5718228). Hiruta et al in its Fig. 1 embodiment is directed to a handheld ultrasound probe 20 with accompanying physical contact pressure or temperature sensor 40(col. 5 lines 42-44) and a control system 39 which is adapted to control between live and freeze frame modes dependent upon sensed contact state. Such a control is necessarily a "power modes" control since one may inherently read 'differently powered modes' for freeze frame and dynamic since at least some different elements are alternatively powered. At least the final step of manufacture, the 'providing' is taught in figs. 1-2

Claims 9, 13-14, 18-19 and 22 - 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Emery (US6610011) which teaches a method for controlling heat buildup in an ultrasound system (col. 1 lines 31-60) including physically sensing engagement of the ultrasound module with the subject (col. 3 lines 35-57) and switching power modes based thereon (col. 5 lines 42 – 57).

Claims 15 ,18, 22-23 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shirasaka (US4945767) directed to power mode switching based upon the number of transducer elements between modes or Miele et al directed to power mode switching of maximum transducer drive signal amplitude, in either case by using a physical array contact sensing element within the probe itself.

Claim Rejections - 35 USC § 103

Claims 4, 6, 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiruta et al or West et al as argued against claim 3 above, further in view of Burke et al(US5517994). Whereas Hiruta et al and West et al are silent in and of themselves as to beamformation (and therefore could conceivably refer to linear step scanning without multiple element beam synthesis), it would have been obvious in view of Burke et al 14 to provide a beamformer in association with an ultrasound probe system, since Burke et al in one embodiment contains an automatic control mode where self-testing of beamformer channels and transducer elements is conducted while the probe is out-of-contact with the patient and imaging is conducted when the probe is contacting a patient (see col. 7 line 47 – col. 8 line 7).

While Hiruta et al and West et al are silent as to the material of the pressure sensor element, the pressure sensor function in Burke et al is served by elements 30 of the actual ultrasound array which detect the contact state or an air mismatch by the number and timing location and amplitude of echo reverberations returning to the array. Under this interpretation in the case of Hiruta et al the patent is being considered for its Fig. 2 embodiment, see col. 6 lines 5-17 where the transducer array includes elements serving the contact discernment function.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hiruta et al or West et al as applied to claim 1 above, and further in view of Whitney et al

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(US5396891). Whereas the former are silent as to the use of manual power control of the ultrasound system, it would have been obvious in view of the latter to provide spring-loaded manual contact switches (manual in the sense of being manually activated by the urging of the transducer assembly against the patient (see col. 2 lines 45-63 and col. 6 line 54 – col. 7 line 39) since this provides failsafe pressure-based system mode activation. Additionally, Hirama et al in col. 3 lines 22 – 32 notes that manual probe head mode switches were themselves well-known in the prior art.

Alternately stated, since the broadest claims are directed to an ultrasound system where an engagement or contact sensor is present and under one interpretation a control system for the ultrasound probe is affected thereby, but the control is not necessarily of a patient-protective or equipment-protective power overload type and therefore might embrace image reproducibility or image mode controls or system self-test controls, then such a mode control application suffices to create anticipation/obvious once other structure limitations are met.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Emery as applied to claim 9 above, and further in view of Miele et al (US5654409). Whereas Emery is silent as to manual effecting of power mode change to reduce heat dissipation, it would have been obvious in view of Miele et al col. 1 lines 31 – 32 to manually effect power shutoff or power mode change responsive to detection of a non-imaging air environment since this was the original way that overheating was addressed prior to automating, i.e. closing the loop for feedback control for this detected state.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Emery as applied to claim 9 above, and further in view of Hiruta et al or West et al or Whitney et al. Whereas the former is confined to physical engagement detection based upon the use of portions of the imaging array itself, it would have been obvious in view of Hiruta et al to use a pressure sensor since Fig.1 thereof is presented as alternative to the Fig. 2 use of the array itself. Alternatively, West et al taught that a concomitant pressure sensing of contact pressure could additionally serve to reproduce measurement conditions with respect to a prior measurement as well as ensure measurement integrity, or Whitney et al taught that a contact pressure threshold could directly switch on the measurement for sake of test coupling sufficiency.

Claims 12, 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Emery as applied to claims 9, 18 above, and further in view of Hirata et al since Hirata et al taught the equivalence of providing thermal or pressure-sensor-based proximity contact sensing in fig. 1 wrt array based contact sensing in Fig. 2.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaka or Miele et al as applied to claim 15 above, and further in view of any one of Hiruta et al or West et al or Whitney et al for reasoning paralleling that set forth against claim 11 above.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shirasaka or Miele et al as applied to claim 15 above, and further in view of Hiruta et al for reasoning paralleling that applied against claim 12 above.

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The following additional art is cited as of interest in relation to transducer contact sensing:

Diagnostic UTS – Hwang et al (US4603702); Therapeutic UTS – Abdelghani (US4708127), Nishimura et al (US6176840), Talish et al (US6261249); Non – UTS diagnosis – Jones (US5924985), Kremenchugsky (US5803915), Donnelly (US4399823); Non-medical, simulator - Stoor et al (US4867168).

.Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

FJJ:fjj

121505


Francis J. Jaworski
Primary Examiner